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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/763,985	02/28/2001	Kyogo Itoh	0020-4817P	3467	
2292 75	590 08/20/2003				
BIRCH STEWART KOLASCH & BIRCH			EXAMINER		
PO BOX 747	CII III 00040 0747	HELMS, LARRY RONALD			
FALLS CHUR	CH, VA 22040-0747				
			ART UNIT	PAPER NUMBER	
			1642		
			DATE MAILED: 08/20/2003	15	

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

	Application No.	Applicant(s)					
Office Action Summary	09/763,985	ITOH ET AL.					
Office Addion Gammary	Examiner	Art Unit					
The MAILING DATE of this communication a	Larry R. Helms	1642					
Period for Reply	ppeare on are cover enects.						
A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a r - If NO period for reply is specified above, the maximum statutory perion - Failure to reply within the set or extended period for reply will, by stated to the second patent term adjustment. See 37 CFR 1.704(b). Status	N. 1.136(a). In no event, however, may a reply within the statutory minimum of thiod will apply and will expire SIX (6) MO tute. cause the application to become A	reply be timely filed irty (30) days will be considered timely. NTHS from the mailing date of this communication. IBANDONED (35 U.S.C. § 133).					
1) Responsive to communication(s) filed on 0	<u>6 June 2003</u>						
2a) This action is FINAL . 2b)⊠	This action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. Disposition of Claims							
4)⊠ Claim(s) <u>3-34</u> is/are pending in the applicat	ion.	·					
4a) Of the above claim(s) <u>6,9-18,20 and 22-</u>	31 is/are withdrawn from co	nsideration.					
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>3-5,7,8,19 and 21</u> is/are rejected.							
7) ☐ Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and	d/or election requirement.						
Application Papers		•					
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on		disapproved by the Examiner.					
If approved, corrected drawings are required in							
12)☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a)⊠ All b)□ Some * c)□ None of:							
1. Certified copies of the priority docume							
2. Certified copies of the priority docume							
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for dome	estic priority under 35 U.S.C	. § 119(e) (to a provisional application).					
a) ☐ The translation of the foreign language [15)☐ Acknowledgment is made of a claim for dome	· · · · · · · · · · · · · · · · · · ·						
Attachment(s)							
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s	5) Notice of	v Summary (PTO-413) Paper No(s) f Informal Patent Application (PTO-152)					
U.S. Patent and Trademark Office PTO-326 (Rev. 04-01) Office	Action Summary	Part of Paper No. 15					

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DETAILED ACTION

- 1. Claims 19, 32-33 have been amended.
- 2. Claims 6, 9-18, 20, 22-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made without traverse in Paper No. 11.
- 3. Claims 3-5, 7-8, 19, 21, 32-34 are under examination.
- 4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
- 5. The following Office Action contains some NEW GROUNDS of rejection.

Rejections Withdrawn

- 6. The rejection of claims 3-5, 7-8, 19, 21, 23-34 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.
- 7. The rejection of claims 3-5, 7-8, 19, 21, 32-34 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

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inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendments to the claims.

- 8. The rejection of claims 3-5, 7-8, 19, 21, 32-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn in view of amendments to the claims and the new ground of rejection under 112 first paragraph.
- 9. The rejection of claims 7-8, 19, 21, 23, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagase et al (DNA Res. 2:167-174, 1995) is withdrawn in view of the new grounds of rejection.
- 10. The rejection of claims 3-5, 7-8, 19, 21, and 32-34 under 35 U.S.C. 103(a) as being unpatentable over Nagase et al (DNA Res. 2:167-174, 1995) as applied to claims 7-8, 19, 21, 32-33 above, and further in view of Campbell (Monoclonal antibody technology, Elsevier Science Publishers, Chapter 1, pages 1-32) and Sambrook et al (Molecular Cloning, A Laboratory Manual, Chapters 3 and 12, 1989) is withdrawn in vie of the new grounds of rejection.

The following are NEW GROUNDS of rejections

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Claim Rejections - 35 USC § 112

11. Claims 3-5, 7-8, 19, 21, 32-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex-parte-Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to pharmaceutical compositions and compositions for treating and preventing cancer with the polynucleotides claimed.

The specification teaches the identification of a tumor antigen peptide, referred to as SART-3 (SQ ID NO:2). The specification further contemplates the use of the DNA molecule encoding the tumor antigen for the immunotherapy of cancer diseases (page 15-18) where "in theory, any method of gene therapy may be used for immunotherapy of cancer based on DNA" (page 16) both *in-vivo* or *in-vitro*. The specification does not enable treatment or prevention of any cancer with the polynucleotides of the invention.

One cannot extrapolate the teachings of the specification to the scope of the claims because the specification provides no exemplification of or guidance on how to

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use the claimed pharmacuetical (i.e. DNA vaccine) for immunization purposes with any predictability and to treat or prevent any cancer in a subject. With regards to tumor immunotherapy, the goal of tumor vaccination is the induction of tumor immunity to prevent tumor recurrence and to eliminate residual disease. However, gene therapy against tumors is highly unpredictable as underscored by Crystal, R.G. (Science, Vol. 270, October 1995, pages 404-410) who teaches that in tumor vaccine studies intended to evoke a tumor-directed immune response, there is no convicining evidence (other than anecdotal case reports) that tumors actually regress, despite the promising observations in experimental animals. In other words, humans are not simply large mice (page 409, 1st column). More recently, Tait et al. (Clin.Canc.Res., Vol. 5, July 1999, pages 1708-1714) revealed just how unpredictable gene therapy was in the clinical setting. The authors' prior phase I trial of 12 patients with extensive ovarian cancer treated with a retroviral vector expressing the BRCA1 splice variant (LXSN-BRCA1sv) demonsrated vector stability, minimal immune response, gene transfer and expression, and some tumor reduction in the patients (page 1708, 2nd column, 2nd paragraph). In contrast, the Phase II trial inititiated in pateints with stage III and IV grade ovarian cancer, showed a high preponderance for vector instability (vector was degraded rapidly), a rapid immunological response invoking neutralizing antibodies to the retroviral vector, and no clinical response to the therapy. Although the difference in response to the therapy may be attributed to differences in immunocompetence between the phase I and II patients (page 1712, 2nd column), the end result seems to indicate that further experimentation is necessary prior to the successful application of

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DNA vaccines, especially with the regards to cancer therapy. There is no suggestion in the specification that the expression of these antigens from the polynucleotide has resulted in autoantibodies against the antigen thus it would be highly unpredictable that administration of the polynucleotide that encodes the antigen as a cancer vaccine, into patients would lead to an effective immune response against the tumor. Further, treatment of cancer in general is at most unpredictable, as underscored by Gura (Science, v278, 1997, pp.1041-1042) who discusses the potential shortcomings of potential anti-cancer agents including extrapolating from in-vitro to in-vivo protocols, the problems of drug testing in knockout mice, and problems associated with clonogenic assays. Indeed, since formal screening began in 1955, thousands of drugs have shown activity in either cell or animal models, but only 39 that are used exclusively for chemotherapy, as opposed to supportive care, have won approval from the FDA (page 1041, 1st column) wherein the fundamental problem in drug discovery for cancer is that the model systems are not predictive. All of this underscores the criticality of providing workable examples which is not disclosed in the specification, particularly in an unpredictable art, such as cancer therapy.

In view of the teachings above, and the lack of guidance and or exemplification in the specification, it would not be predictable for of skill in the art to use the pharmaceutical compositions or vaccine formulations as contemplated in the disclosure. Thus, it would require undue experimentation by one of skill in the art to practice the invention as claimed.

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The response filed 6/6/03 has been carefully considured but is deemed not to be persuasive. The response states that the article of Miyagi et al (Clinical Cancer Res. 7:3950-3962, 2001, attachment to #14) describes the results of peptides derived from SART-3 were administered to cancer patients (see page 10-11of response). In response to this argument, the reference is not on subject because the claims are directed to a polynucleotide administered to the cancer patient and the art does not address this application.

Claim Rejections - 35 USC § 102

12. Claims 7-8, 19, 21, 23, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagase et al (DNA Res. 2:167-174, 1995) as evidenced by Kurshid et al (Analytical Biochemistry 208:138, 1993, abstract).

The claims recite a polynucleotide of SEQ ID NO:1 or a nucleotide of 12 to 2900 of SEQ ID NO:1 wherein the polynucleotide encodes a tumor antigen wherein the tumor antigen protein gives rise to peptide fragments and bind to HLA antigen and are recognized by cytotoxic T lymphocytes and compositions comprising such. For this rejection the intended use of a pharmaceutical composition and pharmaceutical composition for treatments or prevention of tumor is given no patentable weight.

Nagase et al teach a molecule that encodes the identical protein of SEQ ID NO:2. The molecule is identical to the coding region of SEQ ID NO:1 except for one nucleotide (see the attached sequence alignment on the back of this office action). As

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is readily known in the art sequencing errors do exist in polynucleotide sequences as evidenced from Kurshid et al the error rate in nucleotide sequences in ESTs is 2.45 percent. This rate is within the error of one or two nucleotide bases in 3798 bases that are in SEQ ID NO:1. Thus because of errors in the sequencing of polynucleotides it would be concluded that the molecule of Nagase et al is the same as the molecule of the instant applications polynucleotide. In addition, it would be inherent that the protein of Nagase et al would give peptides that would bind to HLA antigen and be recognized by cytotoxic T lymphocytes.

Claim Rejections - 35 USC § 103

13. Claims 3-5, 7-8, 19, 21, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagase et al (DNA Res. 2:167-174, 1995) as applied to claims 7-8, 19, 21, 32-33 above, and further in view of Campbell (Monoclonal antibody technology, Elsevier Science Publishers, Chapter 1, pages 1-32) and Sambrook et al (Molecular Cloning, A Laboratory Manual, Chapters 3 and 12, 1989).

Claims 7-8, 19, 21, 32-33 have been described supra. Claims 3-5, and 34 recite an expression plasmid with the polynucleotide and a transformant transformed with the expression plasmid and a method of producing the protein. For this rejection the intended use of a pharmaceutical composition and pharmaceutical composition for treatments or prevention of tumor is given no patentable weight.

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Nagase et al has been described supra. Nagase et al does not teach an expression plasmid or a transformant with the expression plasmid. This deficiency is made up for in the teachings of Campbell and Sambrook et al.

Campbell teach that it is customary now for any group working on a macromolecule to both clone the genes coding for it an make monoclonal antibodies to it for basic research (see page 29).

Sambrook et al teach expression plasmids and host cells for expression of proteins.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have placed the DNA of Nagase et al in an expression plasmid to produce the protein.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have placed the DNA of Nagase et al in an expression plasmid to produce the protein because Campbell teach it is customary now for any group working on a macromolecule to both clone the genes coding for it an make monoclonal antibodies to it for basic research (see page 29). In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have placed the DNA of Nagase et al in an expression plasmid to produce the protein because Sambrook et la teach expression vectors and methods of expression of the DNA for structural and biochemical analysis (see page 16.2). Thus, It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have placed the DNA of Nagase et al in an expression

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plasmid to produce the protein because it is routinely done in basic research to further characterize the protein.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

The response filed 6/6/03 has been carefully considured but is deemed not to be persuasive. The response states that at the time of the present invention SART-3 was not known in the art to be a tumor antigen protein and there would not be any motivation to use SART-3 for treatment of cancer. As stated in the rejection the intended use of the polynucleotides for treatment or prevention is given no patentable weight for this rejection. Thus, the prior art only need teach the polynucleotide and motivation to place the DNA in a vector for expression which it does as stated above.

Conclusion

- 14. No claim is allowed.
- 15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be

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reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

ARRY R. HELMS, PH.U PRIMARY EXAMINER

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Ohara,O., Nagase,T., Kikuno,R. and Nomura,N.
Direct Submission
Submitted (11-A0G-1995) Osamu Ohara, Kazusa DNA Research Institute,
1532-3, Yana, Kisarazu, Chiba 292-0812, Japan
(E-mail:cdnainfo@kazusa.or.jp, Tel:+81-438-52-3913)
1. 3660
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/db_xref="taxon:9606"
/sex="male"
/cell_line="KG-1"
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/note="KIAA0156 gene |
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                                                                 CTGCTCAGGCTGGAAGGGGAGCTTACCAAGGTGAGGATGGCCCGCCAGGAGAAGAAAAAAA
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        GGCGTGAGCGAGGCGATGGGGATGAGTACGCCATGGCTTCCTCCGCGCAGAGCTCCGCC
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DB

Score 3656.8; Pred. No. 0; 0; Mismatches

96.3%; 99.9%;

Similarity 99.98; Conservative

Match

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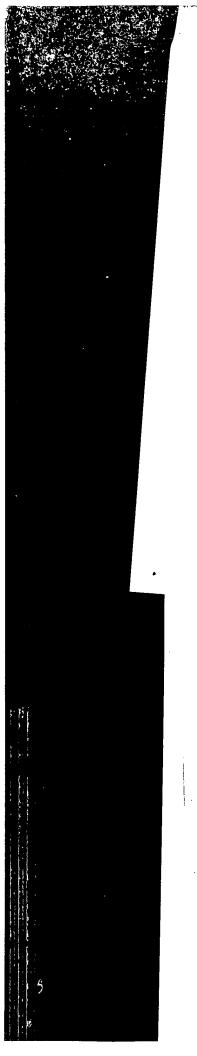
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